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Section II (Amendments to the Claims)

Please cancel claims 1-73, and add new claims 74-108 as set out below in the following listing of claims 1-106 of the application.

1-73. (Canceled)**74. (New)** A gastric occlusive device comprising:

a balloon formed from two vacuum thermoformed half-sections of a multilayer film comprising: (A) a layer of sealing film, having main top and bottom surfaces; and (B) at least one layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces; wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and wherein the at least one layer of thermoplastic polymer film alone lacks such gas barrier character, wherein the half-sections are processed in a vacuum thermoforming die having a substantially non-planar surface, and the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam; and

an inflation element adapted to permit inflation of the balloon within the gastric cavity of a subject for treatment of said subject.

75. (New) The gastric occlusive device of claim 74, wherein the two vacuum thermoformed half-sections are substantially hemispherical in shape.

76. (New) The gastric occlusive device of claim 74, wherein the inflation element comprises a self-healing seal valve adapted to permit the introduction of a fluid into the balloon and retain said introduced fluid within said balloon.

77. (New) The gastric occlusive device of claim 76, further comprising a catheter or liquid feed tube communicatively coupled to the self-healing seal valve.

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78. (New) The gastric occlusive device of claim 76, wherein said fluid comprises a liquid or aqueous substance.

79. (New) The gastric occlusive device of claim 74, wherein the inflation element comprises an effervescent material contained in said balloon, and adapted to liberate gas when contacted with liquid for inflation of the balloon.

80. (New) The gastric occlusive device of claim 79, wherein the effervescent material is substantially centrally located along the substantially non-planar surface and between the two half-sections when said half-sections are bonded to one another to form the peripheral seam.

81. (New) The gastric occlusive device of claim 80, wherein the effervescent material has a longitudinal axis disposed substantially perpendicular to a plane containing the peripheral seam joining the two half-sections

82. (New) The gastric occlusive device of claim 80, wherein the effervescent material is secured to an inner surface of the balloon.

83. (New) The gastric occlusive device of claim 74, wherein said balloon in an inflated state is generally spherical in shape.

84. (New) The gastric occlusive device of claim 83, wherein said balloon in an inflated state has a diameter in a range of from about 3 inches to about 5 inches.

85. (New) The gastric occlusive device of claim 74, wherein said multilayer film has a thickness of up to 10 mils.

86. (New) The gastric occlusive device of claim 74, wherein said sealing film comprises any of polyvinylidene chloride and an ethyl vinyl alcohol polymer, said thermoplastic polymer film comprises polyurethane, and said thermoplastic polymer film is laminated to the sealing film on both the main top and bottom surfaces thereof.

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87. (New) The gastric occlusive device of claim 74, wherein the seam is devoid of any neck or opening therein.

88. (New) The gastric occlusive device of claim 74, wherein said thermoformed half-sections are bonded to one another via radio frequency or ultrasonic welding.

89. (New) The gastric occlusive device of claim 74, comprising a film material providing a seal that is degradable in exposure to physiological components in the gastric cavity of a patient, said film material being adapted to retain the balloon in an inflated state for a predetermined period of time sufficient for said treatment of said patient and to deflate after said period of time by egress of said inflation medium through the film material.

90. (New) The gastric occlusive device of claim 89, wherein said film material comprises an ethylene vinyl acetate / hydroxycellulose blended material.

91. (New) The gastric occlusive device of claim 74, further comprising a coating on an exterior surface of the balloon, said coating comprising a therapeutic agent.

92. (New) The gastric occlusive device of claim 91, wherein said therapeutic agent comprises any of an anti-viral agent, an anti-inflammatory agent, a time-release analgesic formulation, and a clotting agent.

93. (New) The gastric occlusive device of claim 74, wherein said multilayer film comprises an adhesive layer disposed between any of the sealing film and the at least one layer of thermoplastic polymer film.

94. (New) The gastric occlusive device of claim 74, wherein said layer of sealing film is extrusion bonded to said at least one layer of thermoplastic polymer film to form said multilayer film.

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95. (New) A gastric occlusive device comprising:
a balloon formed from two vacuum thermoformed half-sections of a multilayer film having a thickness of up to about 10 mils, the multilayer film comprising: (A) a layer of sealing film comprising any of polyvinylidene chloride and an ethyl vinyl alcohol polymer, the sealing film having main top and bottom surfaces; and (B) at least one layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces; wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and wherein the at least one layer of thermoplastic polymer film alone lacks such gas barrier character, wherein the half-sections are processed in a vacuum thermoforming die having a substantially non-planar surface, and the vacuum thermoformed half-sections are bonded to one another along peripheral portions thereof to form a peripheral seam; and
an inflation element adapted to permit inflation of the balloon within the gastric cavity of a subject for treatment of said subject.
96. (New) The gastric occlusive device of claim 95, wherein the two vacuum thermoformed half-sections are substantially hemispherical in shape.
97. (New) The gastric occlusive device of claim 95, wherein the inflation element comprises a self-healing seal valve adapted to permit the introduction of a fluid into the balloon and retain said introduced fluid within said balloon.
98. (New) The gastric occlusive device of claim 97, further comprising a catheter or liquid feed tube communicatively coupled to the self-healing seal valve.
99. (New) The gastric occlusive device of claim 95, wherein the inflation element comprises an effervescent material contained in said balloon, and adapted to liberate gas when contacted with liquid for inflation of the balloon.
100. (New) The gastric occlusive device of claim 99, wherein the effervescent material is substantially centrally located along the substantially non-planar surface and between the two half-sections when said half-sections are bonded to one another to form the peripheral seam.

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101. (New) The gastric occlusive device of claim 100, wherein the effervescent material has a longitudinal axis disposed substantially perpendicular to a plane containing the peripheral seam joining the two half-sections

102. (New) The gastric occlusive device of claim 95, comprising a film material providing a seal that is degradable in exposure to physiological components in the gastric cavity of a patient, said film material being adapted to retain the balloon in an inflated state for a predetermined period of time sufficient for said treatment of said patient and to deflate after said period of time by egress of said inflation medium through the film material.

103. (New) The gastric occlusive device of claim 95, further comprising a coating on an exterior surface of the balloon, said coating comprising a therapeutic agent.

104. (New) The gastric occlusive device of claim 103, wherein said therapeutic agent comprises any of an anti-viral agent, an anti-inflammatory agent, a time-release analgesic formulation, and a clotting agent.

105. (New) The gastric occlusive device of claim 95, wherein said multilayer film comprises an adhesive layer disposed between any of the sealing film and the at least one layer of thermoplastic polymer film.

106. (New) The gastric occlusive device of claim 95, wherein said balloon in an inflated state has a diameter in a range of from about 3 inches to about 5 inches.

107. (New) The gastric occlusive device of claim 95, wherein the seam is devoid of any neck or opening therein.

108. (New) The gastric occlusive device of claim 95, wherein said thermoformed half-sections are bonded to one another via radio frequency or ultrasonic welding.